

Agriflu[®] Influenza Virus Vaccine, 2010-2011 Formula

Catalog No. NR-31797

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Product Description: NR-31797 is a trivalent inactivated vaccine prepared from influenza viruses A/California/07/2009 NYMC X-181 (H1N1)pdm09, A/Victoria/210/2009 NYMC X-187 (H3N2) (an A/Perth/16/2009-like virus) and B/Brisbane/60/2008 that were predicted to circulate in the United States during the 2010 to 2011 influenza season.

Lot¹: 107001

Manufacturing Date: 2010

TEST	SPECIFICATIONS	RESULTS
Appearance	Report results	Clear and colorless
Hemagglutinin Content A/California/07/2009 NYMC X-181 (H1N1)pdm09 A/Victoria/210/2009 NYMC X-187 (H3N2) B/Brisbane/60/2008	15 µg per syringe 15 µg per syringe 15 µg per syringe	15 µg per syringe 15 µg per syringe 15 µg per syringe
Hemagglutinin Concentration A/California/07/2009 NYMC X-181 (H1N1)pdm09 A/Victoria/210/2009 NYMC X-187 (H3N2) B/Brisbane/60/2008	30 µg per mL 30 µg per mL 30 µg per mL	30 µg per mL 30 µg per mL 30 µg per mL
Residual Components Formaldehyde Polysorbate 80 Cetyltrimethylammonium bromide (CTAB) Neomycin Kanamycin	≤ 10 µg per syringe ≤ 50 µg per syringe ≤ 12 µg per syringe ≤ 0.02 µg per syringe ≤ 0.03 µg per syringe	≤ 10 µg per syringe ≤ 50 µg per syringe ≤ 12 µg per syringe ≤ 0.02 µg per syringe ² ≤ 0.03 µg per syringe ²

¹NR-31797 contains a pre-filled (0.5 mL) syringe.

²Determined by calculation.

Date: 09 MAY 2013

Signature: *Dorothy C. Young*

Title: Technical Manager, BEI Authentication or designee

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